CLAIMS

1. A method for preparing a stabilized azithromycin composition comprising azithromycin monohydrate and at least one excipient, said method comprising exposing the composition with about 40% to about 70% relative humidity at a temperature of about 25°C for a time sufficient to form a stable azithromycin monohydrate composition having a water content from about 6 to about 7 weight percent, based on the total weight of the composition.

2. The method according to Claim 1, wherein the water content is about 6.6 weight percent, based on the total weight of the composition.

3. A method for preparing a stabilized azithromycin composition comprising:
(i) mixing azithromycin monohydrate with at least one excipient in a mixer to form a premix;
(ii) adding sufficient water to the premix formed in Step (i) and mixing to form wet granules; and

(iii) drying the wet granules formed in Step (ii) at a temperature and time sufficient to form an azithromycin monohydrate composition having a water content from about 6 to about 7 weight percent, based on the total weight of the composition, wherein a relative humidity of about 40% to about 70% at a temperature of about 25°C is maintained during Steps (i) and (ii).

4. A stabilized azithromycin composition comprising azithromycin monohydrate and at least one excipient, wherein said composition is prepared by a method comprising exposing the composition with about 40% to about 70% relative humidity at a temperature of about 25°C for a time sufficient to form a stable azithromycin monohydrate composition having a water content from about 6 to about 7 weight percent, based on the total weight of the composition.

5. A stabilized azithromycin composition comprising azithromycin monohydrate and at least one excipient, wherein said composition is prepared by a method comprising:
(i) mixing azithromycin monohydrate with at least one excipient in a mixer to form a premix;
(ii) adding sufficient water to the premix formed in Step (i) and mixing to form wet granules; and
(iii) drying the wet granules formed in Step (ii) at a temperature and time sufficient to form an azithromycin monohydrate composition having a water content from about 6 to about 7 weight percent, based on the total weight of the composition, wherein a relative humidity of about 40% to about 70% at a temperature of about 25°C is maintained during Steps (i) and (ii).

6. The method according to Claim 1, wherein the azithromycin monohydrate is present in an amount of from about 30 to about 85 weight percent.

7. The method according to Claim 1, which is essentially free of an antioxidant.

8. The method according to Claim 1, wherein the azithromycin composition is in the form of an oral dosage form selected from the group consisting of tablets, granules, dragees, hard or soft capsules, powders, multiparticules, and combinations thereof.

9. The method according to Claim 8, wherein the oral dosage form is a tablet.

10. A therapeutic package comprising a container and a stabilized azithromycin composition prepared according to the method of Claim 1.